

**UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESale PRICE
LITIGATION

MDL No. 1456

Civil Action No. 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO:

State of Montana v. Abbott Labs, Inc., et al.,
02-CV-12084-PBS

State of Nevada v. American Home Products
Corp., et al., 02-CV-12086-PBS

**CONSOLIDATED REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS'
MOTION TO DISMISS THE STATE OF MONTANA'S SECOND AMENDED
COMPLAINT AND THE STATE OF NEVADA'S AMENDED COMPLAINT**

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The Nevada and Montana opposition brief improperly conflates the States' flexibility under an approved state Medicaid plan -- which allows the States considerable latitude to define eligibility and covered services and to bring enforcement actions on those matters -- with the exclusively federal Medicaid rebate program operated by HHS. The Medicaid rebate statute -- not a State's Medicaid plan -- defines the term "best price" and requires participating manufacturers to report best price to HHS and execute a contract with HHS. Montana and Nevada rely heavily on citations and cases involving a State's authority under its state Medicaid plan, but the rebate program is based upon a contract between the defendants and the federal government. Under the Medicaid rebate statute, a very particular and unique aspect of the Medicaid program, the manufacturers' obligations are defined exclusively by federal law and contract, and the federal government is the only sovereign designated with oversight and enforcement responsibility. The States do have flexibility under the Medicaid Act to enforce violations of their state Medicaid plans, but they have no discretion under the Medicaid rebate statute because state law and state Medicaid plans have no role in defining obligations under the rebate program, which are defined exclusively by federal law and the federal contract. In fact, in the eleven years since the Medicaid rebate statute was enacted, this is the first time that a State has sought to enforce under state law the obligations to report best price to HHS under the HHS-manufacturer contract. The Court should reject this unprecedented effort by two States and find the state law claims preempted by the federal rebate statute.

Even if the best price claims are not preempted, the States fail to allege the elements of the Nevada and Montana statutes or to satisfy the requirements of Rule 9(b). Remarkably, the States still fail to specify a single allegedly false best price report, the dates or "fraudulent" content of any such report, any discount that should have been included in the best

price calculation, or any “free good,” “rebate,” or “educational grant” that should have been included. That does not come close to satisfying Rule 9(b), even if the States had viable claims under state law.

On the States’ AWP claims, Montana and Nevada do not dispute that their State Medicaid programs had been told by HHS of the “significant differences” between the pharmacies’ acquisition costs and the published AWPs on which the States voluntarily decided to rely to set reimbursement rates. Montana concedes, for example, that it was told seven years ago that the published AWPs exceeded provider purchase prices by as much as 67% for certain generic drugs. The States assert instead that while they were aware of this, they did not know the precise extent of the differences between the AWPs and the provider acquisition costs. But this is irrelevant for purposes of whether the States could have been defrauded by these spreads -- they were plainly “on notice that something may have been amiss,” *Kennedy v. Josephthal & Co.*, 814 F.2d 798, 802 (1st Cir. 1987), and the fact that the spreads on some drugs may have been higher than 67% does not alter the conclusion that the States were aware of a spread and thus cannot recover under their fraud-based theories.

ARGUMENT

I. THE BEST PRICE CLAIMS SHOULD BE DISMISSED.

The States’ conclusory best price claims fail for three reasons. First, they are preempted by the Medicaid rebate statute; second, even if not preempted, these claims fail to allege violations of the Montana and Nevada “deceptive trade practice” statutes, the Montana and Nevada “Medicaid fraud” statutes, and the Montana False Claims Act; and third, even if not preempted and even if the allegations could state claims under the state statutes, the best price “fraud” allegations are far too conclusory to survive Rule 9(b).

A. The State Law Best Price Claims Are Preempted by the Medicaid Rebate Statute and the HHS-Manufacturer Federal Contract.

The States do not contest that the obligation for participating manufacturers to report best price to HHS is defined exclusively by federal law. The States also concede that the term “best price” is defined by federal law and in contracts that each participating manufacturer executes with the federal government. *See* 56 Fed. Reg. 7049 (Feb. 21, 1991) (model Rebate Agreement) (Ex. 1 to Opening Br.); *see also Montana v. Abbot Labs.*, 266 F. Supp. 2d 250, 259 (D. Mass. 2003) (“Montana’s best-price claims require interpretation of contracts to which the Federal Department of Health and Human Services is a party, and the pharmaceutical companies’ best-price obligations under these contracts are governed by federal common law.”). And the States cannot deny that the Medicaid rebate statute confers oversight and enforcement authority only on the federal government. *See* 42 U.S.C. § 1396r-8(b)(3)(B).¹

Instead, Montana and Nevada begin their argument with *Pharmaceutical Research & Manufacturers of America v. Concannon*, 249 F.3d 66 (1st Cir. 2001), *aff’d sub nom. Pharmaceutical Research & Manufacturers of America v. Walsh*, 123 S. Ct. 1855 (2003), but that case did not involve preemption under the Medicaid rebate statute. In *Concannon*, PhRMA challenged Maine’s prior authorization requirement, which the State employed to provide rebates on purchases by non-Medicaid recipients. PhRMA argued that this requirement

¹ The assertion that the rebate statute contemplates state enforcement actions because the statute refers to “other penalties as may be prescribed by law,” 42 U.S.C. § 1396r-8(b)(3)(C)(ii), overlooks the fact that the next sentence of this provision references only a *federal* remedy, the federal Civil Monetary Penalties and Assessment Act. *See id.* (referencing 42 U.S.C. § 1320a-7a). There is simply nothing in the rebate statute that contemplates state actions to enforce the manufacturers’ obligations to the federal government. *See, e.g.*, 42 U.S.C. §§ 1396r-8(b)(3)(B) (empowering the Secretary of HHS to “survey” manufacturers to “verify manufacturer prices,” and authorizing imposition of “civil monetary penalt[ies]” if a manufacturer “refuses a request for information about charges or prices . . . in connection with a survey” or “knowingly provides false information”).

was preempted not because of the Medicaid rebate statute, but because it harmed Medicaid beneficiaries in contravention of the Medicaid Act's requirement that State Medicaid plans be administered "in a manner consistent with . . . the best interests of the recipients.'" *Concannon*, 249 F.3d at 75-78; 42 U.S.C. § 1396a(a)(19). The First Circuit rejected this general Medicaid preemption argument because it found insufficient evidence that Medicaid recipients would be harmed by this particular prior authorization requirement. *See Concannon*, 249 F.3d at 77-78. Neither the First Circuit nor the Supreme Court ever addressed the question of whether the prior authorization requirement was preempted by the Medicaid rebate statute (or, indeed, whether it would have been preempted with a sufficient showing of harm to Medicaid recipients).

For this reason, *Concannon* did not involve, as this case does, a State's attempt to define the obligations of a federal contract or a term defined exclusively by federal law. In fact, the First Circuit in *Concannon* concluded that the prior authorization requirement was "explicitly permitted" by the Medicaid Act. 249 F.3d at 75. In contrast, under the Medicaid rebate statute, States are *not* "explicitly permitted" to define "best price" or bring actions to interpret the obligations of each manufacturer's contract with HHS. Best price and the terms of the HHS contract are governed entirely by federal law.

The States' reliance on *Pharmaceutical Research & Manufacturers of America v. Meadows*, 184 F. Supp. 2d 1186, 1194 (N.D. Fla. 2001), is misplaced for the same reason. There, PhRMA alleged that Florida's method of distributing prescription drugs conflicted with a provision in the Medicaid Act limiting the use of preferred drug formularies. *Meadows*, 184 F. Supp. 2d at 1195. The court held that Florida's program operates as a prior authorization program, not a formulary, and that the State had latitude and discretion under the Medicaid Act's principle of "cooperative federalism." *See id.* at 1195-97. By contrast, under the Medicaid

rebate statute, the States have no latitude or discretion to define best price or bring enforcement actions defining best price and a manufacturer's obligations to HHS.

In this regard, Montana and Nevada continually mischaracterize their action as a traditional "Medicaid fraud" claim permitted by the Medicaid Act's provision relating to actions "in connection . . . with any aspect of the provision of medical assistance and the activities of providers of such assistance" under each State's Medicaid Plan. *See* Opp. at 5 (quoting the Medicaid Act, 42 U.S.C. § 1396b(q)(3)). This case is completely different from the traditional state Medicaid fraud claim against a hospital or nursing home based upon medical services provided under a state Medicaid plan. To the contrary, as the States concede, the Nevada and Montana state Medicaid plans are silent as to each manufacturer's obligations under the Medicaid rebate statute -- those are defined purely by federal law. Although the States do have authority to enforce legitimate components of their state Medicaid plans, the state Medicaid plans have no bearing whatsoever on the federal Medicaid rebate program, as the States acknowledge. Thus, at least for purposes of submitting best price data to the HHS, the participating manufacturers are not acting as "providers" of "medical assistance" under a state Medicaid plan. *Id.*

In contrast to the Medicare program, the Medicaid rebate statute requires the defendant manufacturers to execute a contract with HHS that defines their reporting obligations. In the AWP claims, neither the States nor the class plaintiffs are seeking to define the obligations of a federal contract. As the Supreme Court has recognized, the obligations "to the United States under its contracts" are one of the "few areas" involving such "uniquely federal interests" that "are so committed by the Constitution and laws of the United States to federal control that state law is pre-empted and replaced, where necessary, by federal law." *Boyle v. United Technologies*

Corp., 487 U.S. 500, 504 (1988); *see also id.* at 507, 508 n.4 (because the “imposition of liability on Government contractors [would] directly affect the terms of Government contracts,” the existence of the federal contract was “a significant factor giving broad pre-emptive effect to federal legislation in th[e] field”).

The fact that the Medicaid rebate statute and the HHS contract require manufacturers to report best price data to HHS compels preemption under *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001). Like the fraud-on-the-FDA allegations in *Buckman*, the State’s claims are based upon representations to a federal agency (HHS), not to the State’s Medicaid program or pursuant to a State’s Medicaid plan. *See id.* at 347 (“Policing fraud against federal agencies is hardly a field which the States have traditionally occupied”) (internal quotations and citation omitted); *id.* (“the relationship between a federal agency and the entity it regulates is inherently federal in character”). In fact, just as in *Buckman*, the States’ fraud-on-HHS claims could not exist but for the Medicaid rebate statute. 531 U.S. at 353 (noting that “the fraud claims exist solely by virtue of the FDCA disclosure requirements”). Likewise, just as the FDA had in *Buckman*, HHS has the same kind of oversight and enforcement powers under the rebate program. *See* 42 U.S.C. § 1396r-8(b)(3)(B)-(C) (giving HHS the power to investigate, impose civil money penalties, and exclude a manufacturer from participation). In *Buckman*, the Court held that “[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA’s responsibility to police fraud consistently with the Administration’s judgment and objectives.” 531 U.S. at 350. The States have no answer to why their “[s]tate-law fraud-on-the-[HHS] claims” will not similarly conflict with the federal government’s enforcement “judgment and objectives.”

The Court's ruling that *Buckman* did not apply in the Medicare/AWP context is easily distinguishable, for similar reasons. In contrast to the Medicare program, where the pricing information is supplied to third-party publishers rather than to HHS, the Medicaid rebate statute requires manufacturers to submit best price data directly to HHS. In its Medicare preemption ruling, the Court observed that the AWP claims did not involve pricing data submitted to the government. *See In re Pharm. Indus. Average Wholesale Price Litigation* ("AWP"), 263 F. Supp. 2d 172, 189 (D. Mass. 2003) (citing and distinguishing *Green v. Fund Asset Management., L.P.*, 245 F.2d 214 (3d Cir. 2001), because *Green*, "unlike [*Buckman*]," did not involve "fraud against a federal agency"). But such submissions are at the core of the States' best price claims. This conclusion is not altered just because the States' lawsuit might also result in additional monies for the States. Nor is it the case that if the States' claims are preempted here, then "every" state Medicaid fraud claim would be preempted (Opp. at 6) -- it is just these States' unprecedented claims to enforce the rebate and best price submission obligations to HHS that are preempted.

The States blithely assert that there is no risk of inconsistent adjudication of best price because courts will be applying a uniform federal definition. However, if Montana and Nevada (and other States) can proceed with their claims that each defendant's particular best price submissions violate particular state statutes, with their state-specific definitions of falsity and deception, then different courts will almost certainly reach different conclusions as to how best price should have been calculated for a particular drug. Thus, as the *Buckman* Court recognized, as "a practical matter, complying with [HHS'] detailed regulatory regime in the shadow of 50 States' [laws]" will be impossible. *Buckman*, 531 U.S. at 348, 350. *Cf. Caudill v. Blue Cross & Blue Shield*, 999 F.2d 74, 78-79 (4th Cir. 1993) (recognizing uniquely federal

interests arising out of contract for federal employees' health benefits where "[a]pplication of state law to th[e] federal contract would result in a patchwork quilt of benefits that varied from state to state under the same contract").

Montana and Nevada also incorrectly challenge this Court's prior observation that if the States "were to prevail on the best price claims, it could result in substantial changes in the Medicaid reimbursements paid out by the federal government." *Montana v. Abbot Labs.*, 266 F. Supp. 2d at 259. As the plaintiffs repeatedly observe in other sections of their opposition brief (Opp. at 6, 7), the federal government shares in the cost of paying for prescription drug benefits for Medicaid patients, and if the rebate payments are increased because of the States' lawsuits, then the federal government's share will be impacted as well. *See* 42 U.S.C. § 1396r-8(b)(1)(B) (providing that rebates received by States "shall be considered to be a reduction in the amount expended under the State plan" for purposes of calculating federal medical assistance). The States have no answer to the Medicaid rebate preemption cases, cited in our opening brief,² holding that state law cannot impose changes in those aspects of Medicaid reimbursement that are prescribed by federal law and not left to the States' discretion.

The States' final argument (Opp. at 8), that "no court has ever read the Federal Medicaid Act" as preventing a State from asserting best price violations, is easily explainable: in the 11-year history of the Medicaid rebate statute, no State has ever sought to displace HHS'

² *See Pharmaceutical Soc'y of New York, Inc. v. New York State Dep't of Soc. Servs.*, 1994 WL 33369, at *6 (N.D.N.Y. Jan. 18, 1994), *aff'd*, 50 F.3d 1168 (2d Cir. 1995); *Nebraska Pharmacists' Ass'n v. Nebraska Dep't of Soc. Servs.*, 863 F. Supp. 1037, 1043 (D. Neb. 1994) (state law preempted for impermissible "tinkering with the formulas used to calculate the reimbursement limits"); *Indiana Pharmacists Ass'n v. Indiana Family & Soc. Servs. Admin.*, 881 F. Supp. 395, 398 (S.D. Ind. 1994) (same result).

enforcement role and define the terms of the HHS contract in a lawsuit against participating manufacturers. Montana and Nevada's unprecedented attempt to do so should be dismissed because the state law claims are preempted by the Medicaid rebate statute.

B. Even If Not Preempted, the Best Price Claims Also Fail Under Montana and Nevada Law.

1. Plaintiffs Fail to State Claims Under the Montana and Nevada Medicaid Fraud Statutes.

Montana acknowledges that its Medicaid fraud statute authorizes claims only against persons or entities who have "submit[ted] to a Medicaid agency an application, claim, report, document, or other information that is or may be used to determine . . . the amount of payment under the Medicaid program." Mont. Code Ann. § 53-6-160(1) (2003). Montana concedes that the best price reports are not submitted to the state Medicaid agency (HHS does not share the best price data with the States), but Montana contends that the rebates are still used to determine "the amount of payment" because the rebates affect the "net amount of reimbursements -- or 'payments' -- for each drug." (Opp. at 10). But this conflates the *cost* to the State Medicaid program with the "*payment*" by the State Medicaid program. If Montana's interpretation were correct, then the Montana Medicaid fraud statute would encompass any information conveyed by any person to any entity that somehow affected the State's overall Medicaid costs. The plain language of the Montana statute is not so broad, however. It encompasses only the submission of an "application, claim, report, document, or other information" to the State that is used to "determine . . . the amount of payment under the Medicaid program." Mont. Code Ann. § 53-6-160(1). Montana cannot assert that it uses the best price data or rebate payments to "determine . . . the amount of payment" for drugs under Medicaid. That is fatal to the Montana Medicaid fraud claim.

Nevada's Medicaid fraud claim suffers from a similar defect. Nevada acknowledges that its Medicaid fraud statute is limited to a "claim" "with respect to the [state Medicaid] plan" that "may be used to determine a rate of payment pursuant to the plan." Nev. Rev. Stat. §§ 422.470, 422.480, 422.540(1)(a) (2003). Even if the best price submissions to HHS or the rebate payments to the State could be considered a "claim" -- and they cannot -- neither is "used to determine a rate of payment pursuant to the plan." Nev. Rev. Stat. § 422.470. Nevada, like Montana, conflates the concepts of *cost* to its Medicaid program and "*payment*" pursuant to the plan. While drug rebates may impact the State's total Medicaid expenditures, they do not affect Nevada's "rate of payment" under the plan.³

Once again, the States' argument that they have never been prevented from bringing a Medicaid fraud claim involving Medicaid funds or costs is easily explained -- neither Montana nor Nevada, nor any other State, has ever brought a lawsuit for failing to accurately report best price to HHS.

2. Montana Fails to State a Claim Under Its "False Claims" Act.

Montana acknowledges that its False Claims Act encompasses only those who "knowingly present[] or cause[] to be presented a false, fictitious, or fraudulent claim for allowance or payment to any state agency or its contractors." Mont. Code Ann. § 17-8-231(1) (2003). Montana appears not to dispute that there was no "claim for allowance or payment to any state agency or its contractors." Instead, Montana argues that this Court should construe the Montana statute -- for the first time -- to encompass the same kinds of claims that are allegedly

³ Nevada attempts to draw support from Nev. Rev. Stat. § 422.540(1)(b), (1)(c), and (1)(d) (2003), but those provisions do not apply to the best price claims. Best price data (which Nevada does not even receive) is not used by Nevada "in obtaining or seeking to obtain authorization to provide specific goods," § 422.540(1)(b), is not used "by another in obtaining goods . . . pursuant to the plan," § 422.540(1)(c), and is not used "in qualifying as a provider," § 422.540(1)(d).

covered by the much broader federal False Claims Act and Illinois False Claims Act, which is modeled on the federal statute. Opp. at 12-14 (citing 31 U.S.C. § 3729(33) and 740 Ill. Comp. Stat. 175/3). Montana's assertion that the federal False Claims Act is "analogous" to the Montana False Claims act is belied by even a cursory comparison of the two statutes. Whereas Montana's statute covers only "claim[s] for allowance or payment," Mont. Code Ann. § 17-8-231(1), the federal statute's coverage is much more expansive, encompassing, for example, "record[s] or statement[s] to conceal, avoid, or decrease an obligation to pay . . . the government," 31 U.S.C. § 3729(a)(7). Whereas a claim under the Montana statute is actionable only if submitted to a "state agency or its contractors," Mont. Code Ann. § 17-8-231, the federal statute has no such limitation, *see, e.g.*, 31 U.S.C. § 3729(a)(7). There is simply no justification to rely on federal False Claims Act cases to expand the language of a far narrower state statute. Because the best price HHS submissions are not submitted to any state agency in Montana, and because rebate payments neither "claim specific services or items" nor "determine entitlement to or the rate of payment" under the State's Medicaid program, they cannot form the basis for a claim under Montana's False Claims Act. Mont. Code Ann. §§ 17-8-231(1), 53-6-155(4).

C. The Best Price Claims Are Too Cursory to Survive Dismissal.

Even if not preempted, and even if they satisfy the elements of the state statutes upon which they are based, the best price claims should be dismissed under Rule 9(b). Montana and Nevada cannot dispute that for almost all of the defendants, the Complaint alleges only generalized best price violations, *i.e.*, "each defendant" "reported higher prices" by "exclud[ing] discounts and other inducements offered to physicians." Nev. Cplt. ¶ 392; Mont. Cplt. ¶ 622. Nor can the States dispute that the Complaint fails to specify a *single* allegedly false best price report, the dates or "fraudulent" content of *any* such report, *any* discount that should have been included in the best price calculation, nor *any* "free good," "rebate," "educational grant," or

“credit memo” that should have been included. That does not come close to satisfying Rule 9(b), even if the State had viable claims under state law.⁴

II. THE AWP CLAIMS FAIL UNDER MONTANA AND NEVADA LAW.

A. Montana and Nevada Concede That They Were Aware Of the “Substantial Difference” Between the Published AWPs and the Actual Acquisition Costs of Pharmacies.

Defendants have moved to dismiss the AWP claims asserted by the States on their own behalf on the ground that they were aware of the significant difference between actual acquisition costs and AWP and still decided to use AWP as a basis for Medicaid reimbursement. The States first attempt to characterize this as an estoppel argument. But defendants never contended that the States were legally estopped from asserting any claim. Instead, defendants contend that given the undisputed regulatory history, the States could not have been deceived or defrauded as a matter of law because they have known for decades that the published AWPs for many prescription drugs bear “little relationship to the drugs’ pricing in the marketplace,” Mont. Cplt. ¶ 173; Nev. Cplt. ¶ 136, and yet they voluntarily based reimbursement on AWP.

The States do not dispute the regulatory history set forth in the opening brief, or the fact that HHS audited Montana’s Medicaid program in 1996 and concluded that Montana faced a “significant difference between AWP and pharmacy acquisition costs” and should consider “future changes to pharmacy reimbursement for Medicaid drugs.” Ex. 8 to Opening Br. at 6. Montana concedes, for example, that it was told by HHS that the spreads of some generic drugs were higher than 67%. Instead, the States argue that while they may have known of these

⁴ The States erroneously claim that the magistrate’s recommendation to dismiss the best price claims in *LaCorte v. Merck & Co., Inc.*, No. 99-3807, slip op. at 6 (E.D. La. Aug. 27, 2003), is distinguishable because the magistrate found that the best price data was not in the defendant’s exclusive control. See Pl’s Mem. in Opp. to Def.-Specific Mem. on Mot. to Dismiss at 17. But that is also true here -- HHS has the best price submissions for each defendant.

“significant differences” between AWP and pharmacy acquisition costs, their knowledge is a question of fact because they did not know the *extent* of the differences. *See* Opp. at 17 (asserting that actual acquisition costs “are closely guarded as competitive information”). But the precise amount of the spreads about which the States complain is irrelevant for purposes of whether the States were on notice of the fraud and deception about which they now complain. At a minimum, the regulatory history shows that Montana and Nevada were plainly “on notice that something may have been amiss.” *Kennedy v. Josephthal & Co.*, 814 F.2d 798, 802 (1st Cir. 1987) (noting that parties “need not . . . have fully discovered the nature and extent of the fraud before they were on notice that something may have been amiss”). The fact Montana and Nevada may not have understood the precise amount of the spread on some spreads (*i.e.*, whether it was 70, 80, or 100 percent) does not alter the analysis. *See id.* (noting that parties “need not . . . have fully discovered the nature and extent of the fraud before they were on notice that something may have been amiss”).⁵

The States also confusingly assert that defendants’ regulatory history argument extends to the *parens patriae* claims asserted on behalf of Montana and Nevada residents. It does not -- this argument applies only to the claims asserted on the States’ own behalf. Thus, the States’ reliance (Opp. at 15-16) on what “less sophisticated consumers” knew (as opposed to what the States knew) is irrelevant.⁶

⁵ Montana incorrectly asserts that the defendants did not move to dismiss the States’ own AWP claims based on alleged violations of its False Claims Act and Medicaid fraud statute. As asserted in defendants’ opening brief, these fraud and deception-based claims “cannot survive if the States were aware that the published AWPs bore ‘little relationship to the drugs’ pricing in the marketplace.’” Opening Br. at 13 (quoting *Kennedy v. Josephthal & Co.*, 814 F.2d 798, 802 (1st Cir. 1987)).

⁶ In the consolidated opening brief, Defendants did move to dismiss the *parens patriae* AWP claims asserted under Nevada’s RICO statute, and also on Rule 9(b) grounds to the extent (continued...)

B. Nevada Lacks Standing to Assert Its Racketeering Claim and Alleges No Cognizable Enterprise.

Nevada lacks standing to sue for monetary damages under its civil RICO statute because it is not a “person” entitled to sue. Nev. Rev. Stat. § 207.470(1) (2003). The State points out that “for purposes of Nevada’s *criminal laws*,” Opp. at 19 (emphasis added), “person” is defined to include “this state or any other state, government or county . . . whenever it is used to designate a party whose property may be the subject of an offense.” Nev. Rev. Stat. § 193.0205. Because Nevada’s civil RICO statute is contained within its criminal title, the State argues, the definition contained in § 193.0205 controls. *See* Nev. Rev. Stat. § 193.010 (2003) (“[U]nless the context otherwise requires, the words and terms defined in [Nevada’s criminal title] have the meaning ascribed to them in those sections.”). Here, however, it is clear that the “context otherwise requires.” First, although contained within Nevada’s criminal title, § 207.470 provides for “civil actions” for damages resulting from racketeering. Second, federal courts have construed the federal RICO statute, on which the Nevada RICO statute is “patterned,” *Allum v. Valley Bank of Nevada*, 849 P.2d 297, 301 (Nev. 1993), to bar civil suits for treble damages by the federal government. *See, e.g., United States v. Bonanno Organized Crime Family*, 879 F.2d 20, 21-27 (2d Cir. 1989).

Even if Nevada does have standing to bring a civil RICO action, it has failed to set forth a viable RICO enterprise. Nevada purports to assert a series of 39 “association-in-fact” enterprises involving each of the 13 defendant Companies and each one of three identified publishers of AWP. *See* Nev. Cplt. ¶¶ 449-53. These alleged enterprises are identical to the

they related to PBMs, non-Medicare Part B eligible products, and other alleged “hidden and improper inducements.” *See* Def’s Opening Br. at 19-20. The defendants’ individual briefs also contain particular arguments seeking dismissal of the *parens patriae* AWP claims as they relate to particular Medicare Part B drugs.

“Manufacturer-Publisher Enterprises” alleged by the private plaintiffs in the AMCC, and they fail for the same reasons set forth in support of the motion to dismiss the AMCC.⁷

CONCLUSION

For the reasons stated above and in the Consolidated Memorandum in Support of Defendants’ Motion to Dismiss, Montana’s Second Amended Complaint and Nevada’s Amended Complaint should be dismissed.

⁷ See Consol. Mem. in Support of Def’s Mot. to Dismiss the AMCC at 14-17 (Aug. 1, 2003); Consol. Reply Mem. in Support of Def’s Mot. to Dismiss the AMCC at 6-9 (Sept. 30, 2003).

Respectfully submitted,

**ON BEHALF OF LISTED DEFENDANTS
IN THE ABOVE-CAPTIONED ACTIONS,**

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DATE: November 7, 2003

*Counsel for SmithKline Beecham Corp.,
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CERTIFICATE OF SERVICE

I hereby certify that on November 7, 2003, I caused a true and correct copy of this Consolidated Reply Memorandum in Support of Defendants' Motion to Dismiss the State of Montana's Second Amended Complaint and the State of Nevada's Amended Complaint to be served on all counsel by Verilaw electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL No. 1456.


Mark Seltzer

ON BEHALF OF:

ABBOTT LABORATORIES

AMGEN, INC.

APOTHECON, INC.

ASTRAZENECA PHARMACEUTICALS LP

AVENTIS BEHRING L.L.C.

**AVENTIS PHARMACEUTICALS, INC.
B. BRAUN OF AMERICA**

BAXTER HEALTHCARE CORPORATION

BAXTER INTERNATIONAL, INC.

BAYER CORPORATION

BEDFORD LABORATORIES

BEN VENUE LABORATORIES, INC.

BOEHRINGER INGLEHEIM CORP.

BRISTOL-MYERS SQUIBB CO.

CENTOCOR, INC.

DEY, INC.

GENSIA, INC.

GENSIA SICOR PHARMACEUTICALS, INC.

HOECHST MARION ROUSSEL, INC.

IMMUNEX CORP.

JANSSEN PHARMACEUTICAL PRODUCTS, L.P.

JOHNSON & JOHNSON

MCNEIL-PPC, INC.

NOVARTIS PHARMACEUTICALS CORPORATION

ONCOLOGY THERAPEUTICS NETWORK CORPORATION

ORTHO BIOTECH

PFIZER, INC.

PHARMACIA CORPORATION

PHARMACIA & UPJOHN, INC.

SCHERING-PLOUGH CORPORATION

SICOR INC.⁸

SICOR PHARMACEUTICALS, INC.

SMITHKLINE BEECHAM CORPORATION

TAP PHARMACEUTICAL PRODUCTS, INC.

WARRICK PHARMACEUTICALS CORPORATION

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⁸ SICOR Inc., SICOR Pharmaceuticals, Inc., and their predecessors Gensia Inc. and Gensia Sicor Inc. (collectively "SICOR") did not join in prior pleadings because they had not been served in these matters. As SICOR has now been served in both matters, SICOR hereby joins in Defendants' Consolidated Motion to Dismiss, and Defendants' Consolidated Reply Memorandum.